Steering Committee on Innovation and Regulation in Agriculture

July 26, 2017 Phone Conference

Agenda

- Provide update on development of a proposal for NCSU Center of Excellence
- Present a proposal for a 2017 workshop at NCSU in October
- Proposed addition of two new members

Workshop Recommendations and Identified Needs

From final report:

- Improve understanding and acceptance of agricultural innovations
- Meet needs of the regulatory agencies to facilitate new technology approval
- Improve education and training in regulatory sciences, studies and workforce
- Create framework to support changes in technology regulation and acceptance

Arguments for Center of Excellence for Regulatory Science

- In collaboration with the NCSU College of Ag and Life Sciences new Plant Science Initiative (PSI), facilitate multi-disciplinary research collaborations to address evolving technological and regulatory challenges.
- Develop a program with internal and external partners to increase transparency, improve public understanding and demystify the science of risk assessment
- Prepare for evolving regulatory challenges by improving education/training to increase competencies in Regulatory Science related to agriculture
- Engage EPA, USDA, FDA and other authorities in capacitybuilding needs for assessing new technologies
- Leverage critical mass of ag biotech experts in RTP to participate in research and educational efforts

Activities towards NCSU Center of Excellence for Regulatory Science

- Opened specific discussions with NCSU College of Ag and Life Sciences in May with first meeting in early June
- A writing team has now been formed:
 - Deborah Thompson (lead), Director of Research Partnerships (CALS)
 - David Monks, Asst. Director of Research (CALS), IR-4 Rep to National
 - Danesha Seth Carley, Director Southern Integrated Pest Management
 Center
 - Keith Edmisten, Professor, NCSU Dept. Crop and Soil Science (lead for regulatory science course)
 - Jennifer Kuzma, Professor, NCSU Genetic Engineering and Society Center
 - Chris Hofelt, BASF, US Regulatory Affairs (formerly NCSU)
 - Katherine Drake Stowe, NC Soybean Association
 - Steve Shafer, Chief Scientific Officer, Soil Health Institute
 - Johanna Mirenda, Technical Director, Organic Materials Review Institute
 - Laura McConnell, Bayer, Environmental Safety

Activities towards NCSU Center of Excellence for Regulatory Science

 Conducted a brainstorming session in late June to develop an outline of a proposal. We set a deadline of Aug. 31 to complete.

Activities towards NCSU Center of Excellence for Regulatory Science

- Partial draft distributed July 25 (see attachment), 1.5 hour discussion of writing team was held today
- Updated writing assignments to be distributed to be completed and next draft to be completed by August 18 and final discussion scheduled for August 25.
- This proposal will then be distributed to the Steering Committee for review and to an additional group of reviewers TBD.
- NCSU has a formal procedure for the development of "Centers".
 A decision will be needed whether to pursue formal recognition as a Center by the University.

- Arguments for a second workshop:
 - Maintain momentum and further open lines of communication developed after 2016 workshop
 - Demonstrate the value of collaborative interactions by tackling a topic currently under consideration by EPA
 - Provides and opportunity to promote idea of Center of Excellence for Regulatory Science
 - Could begin to establish an annual workshop series
- Propose to develop a small multi-stakeholder organizing committee to select presenters and invitees. Possible chair could be Professor George Cobb of Baylor, Dept. Environmental Science

- Challenges of Incorporating Higher Tier Study Data for Use in Pesticide Ecological Risk Assessments
 - Hosted by: College of Ag and Life Sciences, North Carolina State University, StateView Hotel, Raleigh, NC
 - October 23-24, 2017

Goals:

- Examine the current regulatory landscape with respect to the use of higher tier studies in environmental risk assessments and identify the greatest challenges.
- Develop a series of recommendations for overcoming the challenges associated with the use of higher tier studies in risk assessment and risk management of pesticides.

Expected Outcomes:

- Report from workshop to be published in an appropriate venue as a means of improving transparency among all stakeholders (publication venue tbd).
- Improved quality and quantity of feedback for regulators and involved stakeholders on both the use, and interpretation of higher tiered studies and pyrethroids, leading to general recommendations that can be implemented for other risk assessments.

- Possible Format for Workshop:
- Pre-workshop participant survey and background materials distributed
- Social event on evening prior to workshop
- Day 1
 - Morning: Opening session, setting the stage for the workshop. Audience limited to workshop participants.
 - Late morning (2-2.5 hour public scientific session) series of scientific lectures addressing various challenging aspects related to pyrethroids risk assessment and risk management and possible solutions. Also include short presentation on new Center of Excellence for Regulatory Science.
 - Afternoon: First Breakout session followed by an initial group discussion
 - Evening: social event
- Day 2
 - Morning and Working Lunch:
 - Second breakout session to develop proposed recommendations with reporting out from each group.
 - Seek consensus on a set of recommendations
- Post workshop Development of Workshop Report
- Target workshop group size ~30 people + facilitators/organizers

Proposed New Members of SC

- Patricia Rice, BASF, Sustainability and Product Stewardship Manager. Scientific background in toxicology, degree from Iowa State. Located in Research Triangle Park, NC.
- Steve Shafer, Chief Scientific Officer, Soil Health Institute, Research Triangle Park, NC. Former Associate Administrator of USDA-ARS in charge of National Programs.